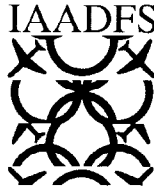


INTERNATIONAL ASSOCIATION OF AIRPORT DUTY FREE STORES

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Dockets Management Branch
[HFA-305]
Food and Drug Administration, 5630 Fishers Lane, Rm 1061
Rockville, Maryland 20852

Reference: Notice of Proposed Rulemaking on Prior Notice of Imported Food
[Docket No. 02N-0278].

Dear Sir or Madam:

The International Association of Airport Duty Free Stores (IAADFS) is pleased to provide comments on the Food and Drug Administration's proposed regulation on Prior Notice of Imported Food under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

IAADFS is the international trade organization comprised of airport duty free enterprises in the Western Hemisphere. Duty free is a unique and important aspect of international trade. It generally offers brands and products of prestigious quality in a pleasant, luxurious and exclusive environment. Airport duty free sales are directed only to international travelers, who as they leave a country may purchase certain pre-defined and limited quantities of merchandise for personal use, free of tax and duty. The industry is important to the economy, creating a positive environment for travel and tourism generally.

FDA Proposed Rule on Prior Notice of Food Imports

Under the FDA's proposed rule, an importer or his agent must submit prior notice to the FDA of all food or beverages imported to the U.S. no later than noon the calendar day before it arrives at the border crossing or port of entry. Any food or beverage imports without adequate prior notice will be held at the port of entry until adequate prior notice is received.

Application to Duty Free: Generally, the range of food products sold in a U.S.-based airport duty free store is limited. It includes packaged chocolates, candies and high-end gourmet specialty foods, and wines and distilled spirits. These items are sold in personal use quantities to travelers departing from the United States. Unlike the proposed FDA registration requirements, which apply to food products "consumed in the U.S.", the FDA "prior notice" rules specifically include imported products that are warehoused for export, even though they are **not** intended for consumption in the U.S.

IAADFS Recommendations: We believe there is merit in the FDA considering a very narrow exclusion to the prior notice rule for products imported for sale [i.e. export] in a duty free store. There are compelling reasons for doing so:

- * The food/beverage items handled in our industry are not consumed in the U.S. All imported products leave the U.S. in small, personal use quantities with departing travelers.
- * Our industry sells only a narrow range of food products [high-end candies, gourmet packaged foods and alcoholic beverages (which are already subject to strict control by ATF)].
- * Our industry is highly regulated by the Customs Service and ATF. In fact, duty free stores are created by statute, with every aspect of their operation governed by specific rules and procedures to ensure that all products sold in a duty free store leave the country. For example, a customer who wishes to make a purchase in a duty free store must show a valid airline ticket and boarding pass before completing the purchase. To further ensure that duty free purchases are not diverted or consumed in the U.S., the duty free store must physically deliver the package

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of purchased items directly to the airline gate to be loaded on the plane as the passenger boards the flight. Customs imposes these and other measures to ensure that the duty- and tax-free products do not in fact enter U.S. commerce.

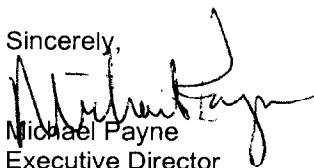
- * For the FDA, it makes sense to provide a limited exception for the narrow range of products that are imported for export through a duty free store, allowing the agency to target its efforts to food products that pose a threat to U.S. security. To the extent that the FDA extends its regulatory net too broadly, it risks becoming overwhelmed and distracted by products that are not a realistic threat to the U.S. food supply, thereby diminishing its effectiveness where it matters most.

In the event the FDA does not exclude duty free store products from the prior notice rule, IAADFS urges the FDA to modify the regulations to better reflect existing commercial practices and to achieve consistency with other government agency requirements. For example:

- * The FDA wants Customs entry data by noon the day before arrival. For duty free, this means the warehouse entry number must be provided. Yet, this number is not even available until the warehouse entry is filed with Customs.
- * Our industry receives food and alcoholic beverages from both Canada and Mexico via truck. Presently, the truck operator presents his documents at the Port of Entry upon his arrival. Since many of our vendors [particularly alcoholic beverage vendors] are located near the border, enforcing a 24-hour advance notice requirement would pose enormous logistical issues for the trade, with resulting confusion and inordinate delays. FDA should consider allowing "low-risk" products [such as alcoholic beverages produced in foreign government-regulated facilities] arriving at a land border crossing to proceed without the 24-hour notice. In any event, we urge the FDA to significantly lessen the notice requirement at land border ports and tailor the rule's application to this type of environment.
- * Duty free stores are required to maintain extensive records to comply with ATF rules. The new FDA requirements applicable to alcoholic beverages should not create duplicative requirements, but instead should be coordinated with the existing ATF requirements.
- * The Customs Service is in the midst of its own rulemaking to require the electronic filing of advance notice of imported products by all modes of transportation and have already implemented such a requirement for ocean cargo. The FDA and Customs need to work together to share the arrival data provided to Customs and to coordinate any additional data requirements needed by the FDA. The whole point of creating a Department of Homeland Security was to streamline, rationalize and coordinate the efforts to secure our borders. It is contrary to this concept for the FDA to establish separate and redundant requirements that increase the costs of business for importers with no meaningful enhancement of security.
- * Customs has developed the highly successful Customs-Trade Partnership Program (CTPAT) which takes into account the importer's compliance rates, their willingness to conduct in-depth analysis into their supply chain, along with other factors. Companies who successfully participate in CTPAT benefit from expedited import processing. This program enhances and strengthens supply chain security and allows Customs to better utilize its limited resources to concentrate on suspect or profiled shipments. It may be useful for the FDA to institute a similar program as it implements these regulations.

IAADFS appreciates the opportunity to comment on the FDA's proposed regulation and we look forward to working with you to develop a final rule that will effectively protect our food supply against terrorist threats without unduly burdening specific industry segments. Please contact our Washington Representative, Jon Kent, at 202-223-6222 if we can be of further assistance.

Sincerely,



Michael Payne
Executive Director